

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY


(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

REC'D 28 JUN 2005

WIPO

PCT

Applicant's or agent's file reference PH0325-PCT	FOR FURTHER ACTION		See Form PCT/PEA/416
International application No. PCT/GB2004/001033	International filing date (day/month/year) 12.03.2004	Priority date (day/month/year) 14.03.2003	
International Patent Classification (IPC) or national classification and IPC G21G4/00, A61K51/00			
Applicant HAMMERSMITH IMANET LTD et al.			
<p>1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of 8 sheets, including this cover sheet.</p> <p>3. This report is also accompanied by ANNEXES, comprising:</p> <p>a. <input checked="" type="checkbox"/> sent to the applicant and to the International Bureau) a total of 11 sheets, as follows:</p> <p><input type="checkbox"/> sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).</p> <p><input checked="" type="checkbox"/> sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.</p> <p>b. <input type="checkbox"/> (sent to the International Bureau only) a total of (indicate type and number of electronic carrier(s)) , containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).</p>			
<p>4. This report contains indications relating to the following items:</p> <p><input checked="" type="checkbox"/> Box No. I Basis of the opinion</p> <p><input type="checkbox"/> Box No. II Priority</p> <p><input type="checkbox"/> Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</p> <p><input checked="" type="checkbox"/> Box No. IV Lack of unity of invention</p> <p><input checked="" type="checkbox"/> Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</p> <p><input type="checkbox"/> Box No. VI Certain documents cited</p> <p><input checked="" type="checkbox"/> Box No. VII Certain defects in the international application</p> <p><input type="checkbox"/> Box No. VIII Certain observations on the international application</p>			
Date of submission of the demand 21.09.2004		Date of completion of this report 27.06.2005	
Name and mailing address of the international preliminary examining authority:  European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465		Authorized Officer Lohberger, S Telephone No. +49 89 2399-6723	



**INTERNATIONAL PRELIMINARY REPORT
ON PATENTABILITY**

International application No.
PCT/GB2004/001033

Box No. I Basis of the report

1. With regard to the **language**, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.
- ☐ This report is based on translations from the original language into the following language , which is the language of a translation furnished for the purposes of:
- ☐ international search (under Rules 12.3 and 23.1(b))
 - ☐ publication of the international application (under Rule 12.4)
 - ☐ international preliminary examination (under Rules 55.2 and/or 55.3)
2. With regard to the **elements*** of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report):*

Description, Pages

1, 2, 4, 7-23	as originally filed
3, 5, 6	received on 12.01.2005 with letter of 11.01.2005

Claims, Numbers

1-33	received on 12.01.2005 with letter of 11.01.2005
------	--

Drawings, Sheets

1/13-13/13	as originally filed
------------	---------------------

- ☐ a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing

3. ☐ The amendments have resulted in the cancellation of:
- ☐ the description, pages
 - ☐ the claims, Nos.
 - ☐ the drawings, sheets/figs
 - ☐ the sequence listing (*specify*):
 - ☐ any table(s) related to sequence listing (*specify*):
4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).
- ☐ the description, pages
 - ☐ the claims, Nos.
 - ☐ the drawings, sheets/figs
 - ☐ the sequence listing (*specify*):
 - ☐ any table(s) related to sequence listing (*specify*):

* If item 4 applies, some or all of these sheets may be marked "superseded."

**INTERNATIONAL PRELIMINARY REPORT
ON PATENTABILITY**

International application No.
PCT/GB2004/001033

Box No. IV Lack of unity of invention

1. ☐ In response to the invitation to restrict or pay additional fees, the applicant has:
- ☐ restricted the claims.
 - ☐ paid additional fees.
 - ☐ paid additional fees under protest.
 - ☐ neither restricted nor paid additional fees.
2. ☐ This Authority found that the requirement of unity of invention is not complied with and chose, according to Rule 68.1, not to invite the applicant to restrict or pay additional fees.
3. This Authority considers that the requirement of unity of invention in accordance with Rules 13.1, 13.2 and 13.3 is
- ☐ complied with.
 - ☒ not complied with for the following reasons:
see separate sheet
4. Consequently, this report has been established in respect of the following parts of the international application:
- ☒ all parts.
 - ☐ the parts relating to claims Nos. .

Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes: Claims	17
	No: Claims	1-16,18-33
Inventive step (IS)	Yes: Claims	17
	No: Claims	1-16,18-33
Industrial applicability (IA)	Yes: Claims	1-33
	No: Claims	

2. Citations and explanations (Rule 70.7):

see separate sheet

Box No. VII Certain defects in the international application

The following defects in the form or contents of the international application have been noted:

see separate sheet

**INTERNATIONAL PRELIMINARY
REPORT ON PATENTABILITY
(SEPARATE SHEET)**

International application No.

PCT/GB2004/001033

Re Item IV.

- 1 The Applicant is informed that claims 18 and 19 are so broad and not linked by a single general inventive concept to present claim 1 that a unity objection must be made (Rule 13.1, 13.2, 13.3 PCT). The reasons are the following:

Claims 18 and 19 relate in a very broad form to computer program arranged to perform **at least some** of the steps indicated in these claims. Some means more than one of these steps, however there are a lot of steps given in these claims which are not linked to the general inventive concept of the radiopharmaceutical generation system given in claim 1.

Re Item V.

- 1 The following documents are referred to in this communication:
D1 : US 4 625 118 A (GAERTNER KARL ET AL) 25 November 1986 (1986-11-25)
D2 : US 6 461 433 B1 (RUSSELL JR JOHN L ET AL) 8 October 2002 (2002-10-08)
D3 : US 6 086 942 A (RUSSELL JR JOHN L ET AL) 11 July 2000 (2000-07-11)
D4 : US 5 371 372 A (PHILLIPS DENNIS R) 6 December 1994 (1994-12-06)
D5 : US 4 455 609 A (SHIGAKI KEISUKE ET AL) 19 June 1984 (1984-06-19)

2 INDEPENDENT CLAIM 1

Having regard to the wording of the amended claims please see objection under Item VII as well.

- 2.1 The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of amended claim 1 is not new in the sense of Article 33(2) PCT.

**INTERNATIONAL PRELIMINARY
REPORT ON PATENTABILITY
(SEPARATE SHEET)**

International application No.

PCT/GB2004/001033

Document D1 discloses (see description column 1, line 55 to column 4, line 30 and claims):

a radio pharmaceutical generation system which is comprised of a fluid processing system with system elements and monitoring software (program control system). The desired quantity is set and controlled which means that the system compares output signals and system elements not being in the expected operative state. This system is suitable for use in administering the radiopharmaceutical to a patient (see column 4, lines 25 to 29). Injection by a needle is the same as administering the radiopharmaceutical to a patient.

- 2.2 The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of claim 1 is not new in the sense of Article 33(2) PCT. Document D2 discloses (see description column 1, line 15 to column 22, line 54 and claims):

a radio pharmaceutical generation system (for brachytherapy) which is comprised of a fluid processing system with system elements and monitoring software (microprocessor program control system). The desired quantity is monitored by a detection system. This means that the system compares output signals and system elements not being in the expected operative state. The final seed is implanted and administered to the patient.

- 2.3 The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of claim 1 is not new in the sense of Article 33(2) PCT. Document D3 discloses (see description column 1, line 1 to column 5, line 65 and claims):

a radio pharmaceutical generation system which is comprised of a fluid processing system with system elements and monitoring software (automated program controlled valves etc.). The desired quantity is set and controlled by radiation detection system with an ionisation chamber. This means that the system compares

output signals and system elements not being in the expected operative state. The final seed is implanted = administered to the patient.

- 2.4 The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of claim 1 is not new in the sense of Article 33(2) PCT.
Document D4 discloses (the whole document):

a radio pharmaceutical generation system which is comprised of a fluid processing system with system elements and monitoring software (program control system for multi valves, temperature etc.). The desired quantity is controlled by a gamma photon detector. This means that the system compares output signals and system elements not being in the expected operative state. The gamma photon detector determines (= controls) the amount of As-72 (see column 8, lines 8 to 13) by measuring, comparing the value with an expected amount and regulating the system). Please see especially the automated system according to figure 2 and column 6, line 49 to column 8, line 18. Temperature is controlled and heaters are adjusted, valves are controlled and operated according to their expected state. As-72 is administered to the patient in liquid form. This fully anticipates present claim 1.

3 INDEPENDENT CLAIM 18

- 3.1 The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of claim 18 is not new in the sense of Article 33(2) PCT.
Documents D1 to D4 all disclose computer programs which perform at least one or more of the steps indicated in present claim 18. (see the respective passages cited in the documents mentioned above).

4 INDEPENDENT CLAIM 19

- 4.1 The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of claim 19 is not new in the sense of Article 33(2) PCT.
Document D2 discloses computer programs which perform at least one of the steps indicated in present claim 19, that is to say it performs these steps when delivering a radiopharmaceutical to a subject (seed tissue). (see the respective passages cited in the documents mentioned above).

5 INDEPENDENT CLAIM 20

- 5.1 The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of claim 20 is not new in the sense of Article 33(2) PCT.
Document D1 to D4 all disclose a radio pharmaceutical generation system which is comprised of a fluid processing system with system elements and monitoring software (program control system for multi valves).

6 INDEPENDENT CLAIMS 22, 23

- 6.1 The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of claims 22 and 23 is not new in the sense of Article 33(2) PCT.
Document D2 still attacks novelty of claim 22 in that this system is not limited to the delivery of the radiopharmaceutical to the patient and therefore the objection must be maintained.
Document D2, D3 and D4 all already disclose a radioactivity detection system in the delivery path (see passages cited above).

7 DEPENDENT CLAIMS 2-16, 21, 24-33

Dependent claims 2-16, 21, 22, 24-33 do not contain any features which, in

**INTERNATIONAL PRELIMINARY
REPORT ON PATENTABILITY
(SEPARATE SHEET)**

International application No.

PCT/GB2004/001033

combination with the features of any claim to which they refer, meet the requirements of the PCT in respect of novelty and/or inventive step (Article 33(2) and (3) PCT).

8 DEPENDENT CLAIM 17

The combination of the features of dependent claim 17 is neither known from, nor rendered obvious by, the available prior art. The reasons are as follows:

a radio pharmaceutical generation system for generating ^{15}O -labelled water as set out in claim 17 is neither disclosed nor rendered obvious by the prior art as presented in the search report.

Re Item VII.

The amended set of claims (claim 1, 13, 18, 19, 20, 22, 23 and 24) is not in accordance with article 28(2) PCT (added subject-matter which goes beyond the content of the application as filed). The expression "for administering a radiopharmaceutical to a patient" cannot be found in the application as filed. The passages given by the Applicant in his letter from 11.1.2005 do not show this feature. The only indication is the delivery to a subject 115 via delivery path 116 which can be found in present description (see figures and page 8).

5 A second problem results from the fact that radioactivity is only measured within the radiopharmaceutical generator itself. The distance between the radiopharmaceutical generator and the subject being examined can be significant, due to logistical constraints (layout, shielding and safety requirements etc.). Thus by the time that the radiopharmaceutical is delivered to the subject, the actual level of radioactivity may be substantially different to the level measured in the radiopharmaceutical generator. For a radiopharmaceutical based on Oxygen-15, which has a half-life of 2 minutes, this distance, and thus decay in radioactivity, can be appreciable.

10 It would thus be desirable to provide a means quantifying the level of radioactivity delivered to the subject.

Summary of the Invention

According to a first aspect of the present invention there is provided a radiopharmaceutical generation system comprising:

15 a fluid processing system for use in administering a radiopharmaceutical to a patient, the fluid processing system being arranged to perform one or more processes in relation to a radiopharmaceutical, and having a plurality of system elements, the fluid processing system being arranged to output signals indicative of a state of the fluid processing system, each of said system elements having an expected operative state; and

20 at least one monitoring software component arranged to derive data from said output signals and to compare said derived data with one or more operating conditions in order to identify system elements not in the expected operative state.

25 The fluid processing system may be a radiopharmaceutical generator, which, in one embodiment is a water generator, and the one or more processes may constitute a radiopharmaceutical generation event.

30 Since the expected operating state of system elements is monitored during a radiopharmaceutical generation event, real-time monitoring of the generator is possible. This means that fault finding and trouble shooting is easier than it is with current systems.

Alternatively, the monitoring software component is arranged to identify which of the processes is currently being performed on the basis of radioactivity data measured by the radioactivity detector, since the radioactivity detector is located in a specific part of the delivery path of the radiopharmaceutical.

5 In the following description, a radiopharmaceutical generator is alternatively referred to as a radiochemistry module.

According to a further aspect of the present invention there is provided a radiopharmaceutical generation system comprising:

a fluid processing system for use in administering a radiopharmaceutical
10 to a patient, the fluid processing system being arranged to perform one or more processes in relation to a radiopharmaceutical, and having at least one actuator element capable of adopting a plurality of operating positions, the fluid processing system being arranged to determine a current operating position of the actuator element and to output a signal indicative of the determined
15 operating position; and

at least one monitoring software component arranged to process data derived from said output signal during execution of said one or more processes in order to identify a state of the fluid processing system.

In this aspect of the invention, the operating positions, or states, of actual
20 devices are determined, which enables accurate pinpointing of faults, together with a means of proactively planning for part replacement. Examples of actuator elements include flow valves, pumping mechanisms, and the like.

According to a yet further aspect of the present invention there is provided a radioactivity detection system for use in relation to a
25 radiopharmaceutical, the detection system comprising:

a fluid processing module arranged to receive a radioisotope and to generate a radiopharmaceutical therefrom;

a radiopharmaceutical delivery system arranged to deliver the generated radiopharmaceutical to a patient, the radiopharmaceutical delivery system
30 comprising a delivery path operable between said fluid processing module and said patient; and

a radioactivity detector arranged to measure radioactivity in the delivery path and output a signal indicative thereof, wherein the radiopharmaceutical delivery system is connectable to said fluid processing module so as to receive the radiopharmaceutical upon generation thereof.

5 The fluid processing module may be a radiopharmaceutical generator, which, in one embodiment is a water generator, and is enclosed within a lead shielding. In a preferred arrangement, the radioactivity detector is located as close to subject as possible thereby quantifying initial radioactivity levels as accurately as possible. More specifically the radioactivity detector is conveniently located along the delivery path at
10 a distance of between 5% and 50% of the delivery path length from the subject, more preferably at a distance of between 7% and 12% of the delivery path length from the subject. In one arrangement, the radioactivity detector is located between 100 and 150 mm from the subject, the delivery path having a total length of approximately 1.2 metres; in a second arrangement the radioactivity detector is located between 300 and
15 350 mm from the subject, the delivery path having a total length of approximately 3.5 metres.

This measured data is then used in the post-processing of scanned images of the subject, thereby increasing the accuracy of quantitative measurements of biological activity of the subject.

20

Brief Description of Drawings

Figure 1 is a schematic diagram of the radiopharmaceutical generator with which embodiments of the invention inter-operate;

25 Figure 2a is a schematic diagram showing the valves of Figure 1 arranged in a first configuration;

Figure 2b is a schematic diagram showing the valves of Figure 1 arranged in a second configuration;

Figure 2c is a schematic diagram showing the valves of Figure 1 arranged in a third configuration;

30 Figure 2d is a schematic diagram showing the valves of Figure 1 arranged in a fourth configuration;

CLAIMS

1. A radiopharmaceutical generation system comprising:
a fluid processing system for use in administering a radiopharmaceutical to a
5 patient, the fluid processing system being arranged to perform one or more
processes in relation to a radiopharmaceutical, and having a plurality of system
elements, the fluid processing system being arranged to output signals indicative of
a state of the fluid processing system, each of said system elements having an
expected operative state; and
10 at least one monitoring software component arranged to derive data from
said output signals and to compare said derived data with one or more operating
conditions in order to identify system elements not in the expected operative state.
2. A system according to claim 1, wherein the or each system element
15 is arranged to receive one or more control signals, the system including a controller
arranged to generate said control signals, wherein said one or more processes are
performed in accordance with said control signals.
3. A system according to claim 2, wherein the controller is arranged to
20 receive said output signals indicative of state of the radiopharmaceutical generation
system.
4. A system according to claim 3, wherein the controller is arranged to
25 track the state of the radiopharmaceutical generation system on the basis of said
received output signals, and transmit data indicative of a state of the fluid
processing system to the monitoring software component in response to a change in
the state of the radiopharmaceutical generation system.

5. A system according to claim any one of claim 2 to claim 4, wherein the signals indicative of a state of the fluid processing system correspond to transmission of control signals to at least one system element.

5 6. A system according to any one of the preceding claims, wherein the monitoring software component is arranged to trigger a termination control signal in response to the derived data satisfying a specified condition, the termination control signal, when received by a system element, causing a currently executing process to terminate.

10

7. A system according to any one of the preceding claims, wherein the monitoring software component is arranged to trigger a termination control signal to each of said system elements identified as not being in the expected operative state, the termination control signal, when received by said system element, causing a
15 currently executing process to terminate.

8. A system according to any one of the preceding claims, including alerting means arranged to generate an alert in response to the monitoring software component identifying that one of said system elements is not in the expected
20 operative state.

9. A system according to any one of the preceding claims, wherein the monitoring software component is arranged to process said data derived from said output signals in order to identify a state of the fluid processing system.

25

10. A system according to claim 9, including an outputting software component arranged to output data indicative of the identified state.

11. A system according to claim 10, wherein the outputting software component includes display means arranged to display the data indicative of the identified state.

5 12. A system according to claim 11, wherein the display means is arranged to display a natural language descriptor corresponding to said identified state.

10 13. A system according to any one of the preceding claims, wherein the fluid processing system includes: a heating device; a radiopharmaceutical delivery system comprising an output to said patient; a plurality of valves arranged to control the path of the delivery system; a dialyser; a pump for pumping the radiopharmaceutical around the delivery system; and at least one radioactivity detector arranged in the path of the radiopharmaceutical delivery path.

15 14. A system according to claim 13, wherein the fluid processing system is operable to output signals indicative of at least some of: temperature of heating device; energised status of the valves; flow rate through, and pressure applied by, the pump; radioactivity measured by radioactivity detector; and time elapsed since
20 the process started.

15 15. A system according to claim 14, wherein the monitoring software component is arranged to identify which of the processes is currently being performed on the basis of data identifying the energised status of the valves.

25 16. A system according to any one of claim 13 to claim 15, wherein the monitoring software is arranged to compare data derived in respect of the pump pressure and data derived in respect of the flow rate with specified operating limits,

and, in the event that one or both of the pressure and/or flow rate fall outside of the operating limits, to generate an alert.

17. A system according to any one of the preceding claims, wherein the
5 radiopharmaceutical comprises ^{15}O -labelled water.

18. A computer program product arranged to perform at least some of the steps of:

generating a plurality of control signals for use in control of a fluid
10 processing system when delivering a radiopharmaceutical to a patient;

transmitting said generated control signals to a plurality of system elements in the fluid processing system;

communicating data indicative of at least some of said generated control signals to a monitoring system;

15 processing the communicated data so as to identify expected operating states of said system elements;

receiving data indicative of operating states of said system elements during delivery of said radiopharmaceutical to said patient;

20 comparing the received data against one or more predetermined conditions based on the expected operating states, and, in response to the received data indicating that one or more of the system elements is not in the expected state, transmitting data indicative thereof to the monitoring system.

19. A computer program product arranged to perform at least some of
25 the steps of:

transmitting specified operating conditions to a controller for use in formulating control signals for controlling a fluid processing system when delivering a radiopharmaceutical to a patient;

receiving data indicative of a state of the fluid processing system during delivery of said radiopharmaceutical to said patient;
evaluating said received data in accordance with specified conditions; and
generating user-perceptible output indicative of the evaluated data.

5.

20. A radiopharmaceutical generation system comprising:
a fluid processing system for use in administering a radiopharmaceutical to a patient, the fluid processing system being arranged to perform one or more processes in relation to a radiopharmaceutical, and having at least one actuator
10 element capable of adopting a plurality of operating positions, the fluid processing system being arranged to determine a current operating position of the actuator element and to output a signal indicative of the determined operating position; and
at least one monitoring software component arranged to process data derived from said output signal during execution of said one or more processes in
15 order to identify a state of the fluid processing system.

21. A system according to claim 20, wherein said actuator elements include valve elements.

20

22. A radiopharmaceutical generation system comprising:
a fluid processing system for use in administering a pharmaceutical to a patient, the fluid processing system being arranged to perform one or more processes in relation to a radiopharmaceutical in accordance with a plurality of control signals, and having a plurality of system elements, the fluid processing
25 system being arranged to output signals indicative of a state of the fluid processing system, each of said system elements having an expected operative state;
a controller arranged to control the fluid processing system, the controller having at least one control software component arranged to generate at least some of said control signals;

a monitoring software component arranged to receive data in relation to the state of the radiopharmaceutical generation system,

wherein the controller is arranged to track the state of the radiopharmaceutical generation system during delivery of said radiopharmaceutical and to output data indicative of the same to the monitoring software component, the
5 monitoring software component being arranged to compare said output data with one or more operating conditions in order to identify system elements not in the expected operative state.

10 23. A radioactivity detection system for use in relation to a radiopharmaceutical, the detection system comprising:

a fluid processing module arranged to receive a radioisotope and to generate a radiopharmaceutical therefrom;

a radiopharmaceutical delivery system arranged to deliver the generated
15 radiopharmaceutical to a patient, the radiopharmaceutical delivery system comprising a delivery path operable between said fluid processing module and said patient; and

a radioactivity detector arranged to measure radioactivity in the delivery path and output a signal indicative thereof,

20 wherein the radiopharmaceutical delivery system is connectable to said fluid processing module so as to receive the radio pharmaceutical upon generation thereof.

24. A radioactivity detection system according to claim 23, wherein the
25 radioactivity detector is located along the delivery path at a distance of between 5% and 50% of the delivery path length from the patient, more preferably at a distance of between 7% and 12% of the delivery path length from the subject.

25. A radioactivity detection system according to claim 23 or claim 24, wherein the radioactivity detection system includes a processing system arranged to process said output signal.

5 26. A radioactivity detection system according to any one of claims 23 to 25, wherein the fluid processing module includes a module radioactivity detector therein, said module radioactivity detector being arranged to measure radioactivity in the fluid processing module and output a signal indicative thereof, wherein the processing system is arranged to process said output signal.

10

27. A radioactivity detection system according to claim 26, wherein the processing system is arranged to compare signals received from the radioactivity detector and said module radioactivity detector.

15

28. A radioactivity detection system according to claim 27, wherein an output signal comprises a plurality of signal components, and, for at least one such signal component received from the module radioactivity detector, the processing system is arranged to identify a corresponding component in the signal received from the radioactivity detector.

20

29. A radioactivity detection system according to claim 27 or claim 28, wherein, for at least one such signal component received from the module radioactivity detector, the processing system is arranged to identify the temporal delay between detection thereof and detection of a corresponding component in the signal received from the radioactivity detector.

25

30. A radioactivity detection system according to any one of claim 26 to claim 29, wherein the processing system is arranged to receive data indicative of distance between the radioactivity detector and said module radioactivity detector.

31. A radioactivity detection system according to claim 30 when dependent on any one of claim 27 to claim 29, wherein, for any signal component of the signal received from the radioactivity detector, the processing system is
5 arranged to estimate an expected delay in occurrence thereof in relation to a corresponding component of the signal received from the module radioactivity detector, based on the distance data, and to compare the identified temporal delay corresponding to the signal component with the estimated delay.

10 32. A radioactivity detection system according to claim 30 or claim 31 when claim 30 is dependent on any one of claim 27 to claim 29, wherein, for any signal component of the signal received from the module radioactivity detector, the processing system is arranged to estimate an expected radioactivity value, based on
15 the half-life of the radioisotope and the distance data, and to compare the signal component with the estimated radioactivity value.

33. A radioactivity detection system according to any one of claim 23 to claim 32, wherein the fluid processing module includes: a heating device; a plurality of valves arranged to control the path of the delivery system; a dialyser;
20 and a pump for pumping the radiopharmaceutical around the delivery system.